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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

MINDY BIRDWELL,

Plaintiff,

vs.

AMERICAN MEDICAL SYSTEMS, INC.; AMERICAN MEDICAL SYSTEMS, LLC, INDIVIDUALLY AND F/K/A AMERICAN MEDICAL SYSTEMS, INC.; AMERICAN MEDICAL SYSTEMS HOLDINGS, INC.; ASTORA WOMEN'S HEALTH, INC.; ASTORA WOMEN'S HEALTH LLC; ASTORA WOMEN'S HEALTH HOLDINGS, LLC; ASTORA HOLDINGS, LLC,

Defendants.

Case No.:
COMPLAINT WITH JURY DEMAND

I. CIVIL ACTION COMPLAINT

Plaintiff, MINDY BIRDWELL ("Plaintiff"), by and through her counsel, brings this Complaint against Defendants' AMERICAN MEDICAL SYSTEMS, INC., AMERICAN

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MEDICAL SYSTEMS, LLC individually and f/k/a American Medical Systems, Inc., AMERICAN MEDICAL SYSTEMS HOLDINGS, INC., ASTORA WOMEN'S HEALTH, INC., ASTORA WOMEN'S HEALTH LLC, ASTORA WOMEN'S HEALTH HOLDINGS LLC and ASTORA HOLDINGS (collectively, "Defendants'", as the context may require) for injuries suffered as a result of defective pelvic mesh products designed, manufactured and marketed by Defendants, and implanted in Plaintiff. In support, Plaintiff states and avers as follows:

II. PARTIES

1. Plaintiff MINDY BIRDWELL, is, and was, at all relevant times, a resident of the state of Oregon.

2. Defendant, American Medical Systems, Inc. ("AMS) is a wholly owned subsidiary of Defendant American Medical Systems Holdings Inc. and is a foreign corporation with its principal offices in Minnesota.

3. Defendant American Medical Systems, LLC, ("AMS LLC") is a foreign corporation with its

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principal office in Delaware.

4. Defendant American Medical Systems Holdings Inc., ("AMS HOLDINGS") is a foreign corporation with its principal office in Minnesota.

5. Defendant Astora Women's Health, Inc., ("ASTORA") was a foreign corporation with its principal office in Minnesota.

6. Defendant Astora Women's Health LLC, ("ASTORA LLC") is a foreign corporation with its principal office in Minnesota.

7. Defendant Astora Women's Health Holdings, LLC, ("ASTORA HOLDINGS LLC") is a foreign corporation registered in Delaware.

8. Defendant Astora Holdings, LLC ("ASTORA HOLDINGS LLC") is a foreign corporation registered in Delaware.

9. Defendants share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution and sale of the

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medical device line at issue in this litigation and shall be referenced collectively hereinafter as "Defendants".

10. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

III. JURISDICTION AND VENUE

11. Damages sought in this matter are in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

12. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

13. Venue is proper in the Eastern District Court of Washington pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to this

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claim occurred in this district.

14. Defendants conducted substantial business in the State of Washington and in this District, distribute Pelvic Mesh Products in this District, receive substantial compensation and profits from sales of Pelvic Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District.

15. Defendants conducted business in the State of Washington through sales representatives and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and/or selling, either directly or indirectly, and/or through third parties or related entities, Pelvic Mesh Products; thus, there exists a sufficient nexus between Defendant forum contacts and the Plaintiff's claims to justify assertion of jurisdiction in Washington.

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16. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Washington such that requiring an appearance does not offend traditional notices of fair play and substantial justice.

IV. DEFENDANTS' PELVIC MESH PRODUCTS

17. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the Monarc Sling System ("Monarc"). The Monarc is represented by Defendants to correct and restore normal pelvic function by implantation of polypropylene mesh in the pelvis tethered in place by two arms that extend up through a woman's pelvis. The Monarc was specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue

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reactions, minimal tissue trauma, and minimal pain while correcting urinary incontinence.

18. Prior to the implantation of the Monarc at issue in this claim, Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the Monarc under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

19. Despite claims that the monofilament polypropylene mesh in the Monarc is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response. This immune response promotes degradation of the mesh material and can contribute to the formation of severe adverse reactions to the mesh.

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20. The Monarc was marketed to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by safe, effective, and minimally invasive surgical techniques.

21. Defendants marketed and sold the Monarc through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety, utility, and efficacy of the Monarc and its other transvaginal mesh products.

22. Contrary to the representations and marketing of Defendants, the Monarc has high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitating revision surgeries, and has caused severe and irreversible injuries, conditions, and damage to a significant

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number of women, including Plaintiff Birdwell. The defects stem from many issues, including:

a. The use of polypropylene material in the Monarc and the immune reaction that results;

b. the design of the Monarc to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

c. the contraction and/or shrinkage of the mesh and surrounding scar tissue;

d. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade and the device to migrate into organs and surrounding structures;

e. the use and design of anchors in the Monarc that when placed correctly are likely to pass

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through and injure major nerve routes in the pelvic region;

f. degradation of the mesh itself over time which causes the internal tissue to degrade;

g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

h. the design of the trocars (devices used to insert the Monarc into the vagina) requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings.

23. Upon information and belief, Defendants has consistently underreported and withheld information about the propensity of its Monarc to fail and to cause injury and complications and has misrepresented the efficacy and safety of its transvaginal mesh products, including the Monarc, through various means and media, actively and intentionally misleading the

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public.

24. Despite the chronic underreporting of adverse events associated with the Monarc, enough complaints were recorded for the Food and Drug Administration ("FDA") to issue a public health notification regarding the dangers of these devices.

25. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to the Monarc and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Defendants is one of the manufacturers of the products that are the subject of the notification.

26. On July 13, 2011, the FDA issued a Safety Communication entitled, "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein,

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the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of "continuing serious concern." (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse were "not rare." These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse

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repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011 was known or knowable to Defendants and was not disclosed in any manner.

27. Defendants have further known the following:

a. that some of the predicate devices for the Monarc had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the Monarc and some or all

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of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that its transvaginal mesh products, including thee Monarc, were and are causing numerous patients severe injuries and complications.

28. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff Birdwell. As a result, Defendants actively and intentionally misled and continues to mislead the public into believing that its transvaginal mesh products, including the Monarc, and the procedures for implantation were and are safe and effective.

29. Defendants failed to perform or rely on proper and adequate testing and research in order to

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determine and evaluate the risks and benefits of the Monarc.

30. Defendants failed to design and establish a safe, effective procedure for removal of the Monarc; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Monarc or parts thereof.

31. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for repair of pelvic organ prolapse and stress urinary incontinence have existed at all times relevant to this matter.

32. The Monarc was at all times utilized and implanted in a manner foreseeable to Defendants, as they generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

33. Defendants provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the

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Monarc, and thus increase the sales of these products.

34. The Monarc implanted into Plaintiff Birdwell was in the same or substantially similar condition as when it left the possession of Defendants, as well as being in the condition directed by and expected by this Defendant.

35. Plaintiff Birdwell and her physicians foreseeably used and implanted the Monarc, and did not misuse or alter these products in an unforeseeable manner.

36. The injuries, conditions, and complications suffered by women who have been implanted with the Monarc include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, recurrent and chronic infections, and prolapse of organs. In many cases, these women

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have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

37. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Monarc) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

38. Defendants knew and had reason to know that the Monarc could and would cause severe and grievous personal injury to the users/recipients of the Monarc, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

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39. At all relevant times herein, Defendants continued to promote Monarc as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

40. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff Birdwell and the public on notice of the dangers and adverse effects caused by implantation of the Monarc.

41. The Monarc was defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing.

42. The products known as Monarc, as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendants' Pelvic Mesh Products or the Pelvic Mesh Products.

43. Defendants' Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed,

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and sold and distributed by the Defendants, at all times relevant herein.

V. FACTUAL BACKGROUND

44. On July 8, 2010, Plaintiff was implanted with an AMS Monarc, Lot No. 65842208, Ref No. 72403830, ("Monarc" or "Pelvic Mesh Product", and/or "Product") during surgery performed at Providence St. Mary Medical Center in Walla Walla, Washington.

45. The Pelvic Mesh Products were implanted in Plaintiff to treat her pelvic organ prolapse, the use for which the Pelvic Mesh Products were designed, marketed and sold.

46. On June 27, 2020, Plaintiff underwent revision surgery of the AMS Monarc at Providence St. Mary Medical Center in Walla Walla, Washington.

47. As a result of having the Product implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury and permanent and substantial physical deformity and has suffered financial or

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economic loss, including, but not limited to, obligations for medical services and expenses.

48. Defendants' Pelvic Mesh Product has been and continues to be marketed to the medical community and to patients as a safe, effective, reliable, medical device; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

49. The Defendants have marketed and sold the Defendants' Pelvic Mesh Product to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and

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include the provision of valuable consideration and benefits to health care providers. Also utilized are documents, brochures, websites, and telephone information lines, offering exaggerated and misleading expectations as to the safety and utility of the Defendants' Pelvic Mesh Product.

50. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Pelvic Mesh Product has high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff.

51. The Defendants have consistently underreported and withheld information about the propensity of Defendants' Pelvic Mesh Product to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Product,

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through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

52. Defendants have known and continue to know that their disclosures to the FDA were and are incomplete and misleading; and that the Defendants' Pelvic Mesh Product was and is causing numerous patients' severe injuries and complications. The Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Defendants' Pelvic Mesh Product was and is safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Product into the Plaintiff.

53. Defendants failed to perform or rely on

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proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' Pelvic Mesh Product.

54. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' Pelvic Mesh Product; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' Pelvic Mesh Product.

55. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar other conditions have existed at all times relevant as compared to the Defendants' Pelvic Mesh Product.

56. The Defendants' Pelvic Mesh Product was at all times utilized and implanted in a manner foreseeable to the Defendants.

57. The Defendants have at all times provided

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incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' Pelvic Mesh Product, and thus increase the sales of the Product, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

58. The Pelvic Mesh Product implanted into the Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by the Defendants.

59. The injuries, conditions, and complications suffered due to Defendants' Pelvic Mesh Product include but are not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, pelvic pain, urinary and fecal incontinence, prolapse

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of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to Plaintiff's intimate partners.

60. Despite Defendants' knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Product, the Defendants have, and continue to manufacture, market, and sell the Product, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to the Defendants' Pelvic Mesh Product, both prior to and after the marketing and sale of the Product.

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VI. FIRST CAUSE OF ACTION
WASHINGTON PRODUCT LIABILITY ACT

61. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

62. At all times relevant to this litigation, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting its medical device products.

63. At all times relevant to this litigation, Defendant designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and distributed the medical device used by Plaintiff as described above.

64. At all times relevant to this litigation, Defendant's medical device was expected to reach and did reach the intended consumers, handlers, and users or other persons coming into contact with these

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products in Washington and throughout the United States, including Plaintiffs, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendant.

65. In violation of the Washington Products Liability Act ("WPLA"), RCW 7.72, et seq., at all times relevant to this action, at the time Defendant's medical device left control of Defendant, it was defective and not reasonably safe. These defects include, but are not limited to, the following:

a) Defendant is strictly liable for Plaintiffs' injuries and damages because at the time of manufacture, and at the time Defendant's medical device left control of Defendant, the likelihood that the medical device would cause injury or damage similar to that suffered by Plaintiffs, and the seriousness of such injury or damage had been known by Defendant and outweighed the burden on Defendant to design a product that would have prevented Plaintiffs' injuries and damages and outweighed the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the subject product.

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b) Defendant's medical device is unsafe to an extent beyond that which would be contemplated by an ordinary consumer.

c) The medical device manufactured and/or supplied by Defendant was defective in design in that, an alternative design and/or formulation exists that would prevent severe and permanent injury. Indeed, at the time that Defendant designed its medical device, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

d) The medical device was not reasonably safe in design under the WPLA.

e) The medical device manufactured and/or supplied by Defendant was not reasonably safe because Defendant did not provide an adequate warning or instruction about the product. At the time the medical device left Defendant's control, the device possessed dangerous characteristics and Defendant failed to use reasonable care to provide an adequate warning of such characteristics and their danger to users and handlers of the product. The medical device is not safe and cause severe and permanent injuries. The medical device was not reasonably safe because the warning was inadequate, and Defendant could have provided adequate warnings or instructions.

f) The medical device that was manufactured and/or supplied by

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Defendant was not reasonably safe because adequate warnings or manufacturer instructions were not provided after the medical device was manufactured and when Defendant learned of, or should have learned of, the dangers connected with the medical device.

g) The medical device manufactured and/or supplied by Defendant was not reasonably safe because it did not conform to an express warranty made by Defendant regarding the product's safety and fitness for use. Defendant expressly warranted that the medical device was safe and fit for their intended purposes, that it was of merchantable quality, that it was not produce any dangerous side effects, that they were adequately tested, and that the device was safe to human health and the environment, and effective, fit, and proper for its intended use. Defendant did not disclose the material risks that its medical device could cause severe and permanent injury. Defendant's express warranty induced Plaintiff to use the device, and Plaintiff's damages were proximately caused because Defendant's express warranty was untrue. The mesh product was not reasonably safe because of nonconformity to express warranty under the WPLA.

66. As a direct and proximate result of Defendant placing its defective medical device into the stream

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of commerce, Plaintiff suffered grave injuries, and endured physical and emotional pain and discomfort, as well as economic hardship, including considerable financial expenses for medical care and treatment and other damages further discussed in herein.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

VII. SECOND CAUSE OF ACTION VIOLATION OF THE WASHINGTON CONSUMER PROTECTION ACT

67. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

68. Plaintiff purchased and used the Defendants' Pelvic Mesh Product primarily for personal use and thereby suffered ascertainable losses as a result of

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Defendants' actions in violation of the consumer protection laws.

69. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' Pelvic Mesh Product, and would not have incurred related medical costs and injury.

70. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Pelvic Mesh Product that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

a) Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

b) Representing that goods or services has characteristics, ingredients, uses benefits or quantities that they do not have;

c) Advertising goods or services with the intent not to sell them as advertised; and,

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d) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

71. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Pelvic Mesh Product. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Pelvic Mesh Product.

72. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Product.

73. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Product, and would not have incurred related medical costs.

74. Defendants' deceptive, unconscionable, or

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fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

75. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

76. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

77. Under applicable state statutes enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable

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consumer sales practices.

78. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Pelvic Mesh Product was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

79. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

80. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Pelvic Mesh Product and failed to take any action to

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cure such defective and dangerous conditions.

81. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

82. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

83. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

84. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against

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Defendants, and each of them, individually, jointly, severally and in the alternative, and request restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

VIII. PUNITIVE DAMAGES

85. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

86. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants'

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standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

87. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

88. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

89. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken

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singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

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A. All general, statutory, and compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all injuries and damages, both past and present;

B. All special and economic damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages, pain and suffering;

C. Attorneys' fees, expenses, and costs of this action;

D. Double or triple damages as allowed by law;

E. Punitive and/or exemplary damages;

F. Pre-judgment and post-judgment interest in the maximum amount allowed by land; and

G. Such further relief as this Court deems necessary, just, and proper.

X. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

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Dated this 15th day of March, 2022.

CORRIE YACKULIC LAW FIRM, PLLC

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